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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,498	05/15/2001	John E. Sims	0317-US	8629

22932 7590 07/02/2002

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EXAMINER
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ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary	Application No. 09/763,498	Applicant(s) Sims et al.
	Examiner Fozia Hamud	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 25, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *21-43* is/are pending in the application.

4a) Of the above, claim(s) *40-43* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *21-26, 29, and 32-38* is/are rejected.

7) ☒ Claim(s) *27, 28, 30, 31, and 39* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicants' election with traverse of the invention of Group II (claims 21, 23, 25, 26, and 31), in Paper No. 8, filed on 28 May 2002 is acknowledged.

Applicants' ground of traversal is that the nucleic acids of SEQ ID NO:5 are fully contained within the nucleic acids of SEQ ID Nos: 7 and 12 and that SEQ ID NO:7 and SEQ ID NO:12 only differ by a single nucleic acid. Thus Applicants argue that the nucleic acid molecules of SEQ ID Nos: 7 and 12 are structurally similar, therefore, there are no basis for restricting these nucleic acid molecules. Secondly, Applicants direct the Examiners attention to Annex B Unity of Invention (PCT/AI/1 Rev.1), Example 17, which describes that unity between a protein X and the DNA encoding it.

Firstly, Applicants' argument that the polynucleotide of SEQ ID NO:12 is an IL-1 Epsilon polymorphism and that said polynucleotide and the polynucleotide of SEQ ID NO:7 share considerable structural similarities is persuasive. Therefore, the nucleic acid molecules of SEQ ID Nos: 5, 7 and 12 encoding the polynucleotides of SEQ ID Nos:6, 8 and 13 respectively, and method of producing the encoded proteins will be all searched and examined. Secondly, the Examiner agrees with Applicants that Example 17 of Annex B Unity of Invention, does describe unity of invention between a protein and the DNA encoding it, and since Applicants' argument that the nucleic acid molecules of SEQ ID NOS:5, 7 and 12 share common structural properties which distinguish them from structurally related prior art nucleic acids was persuasive, then the polypeptides encoded by said nucleic acids and methods of producing said polypeptides also share unity with said nucleic acids

. Thus Groups I-III which are drawn to the isolated nucleic acids of SEQ ID Nos: 5, 7, 12, Groups IV-V which are drawn to polypeptides of SEQ ID Nos:, 8 and 13 and Groups VI-VII which are drawn to method of producing the polypeptide encoded by the nucleic acids of SEQ ID NOS: 7 and 8 will all be combined. As a result claims 21-39 are drawn to the elected invention.

Claims 40-43 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

New Groups:

Group I Claims 21-39, drawn to an isolated nucleic acid molecules, encoding the polypeptides of SEQ ID NO:6, 8 and 13, said nucleic acid molecules comprising the nucleotide sequences set forth in SEQ ID NO:5, 7 and 12 respectively, an expression vector comprising said nucleic acids, a host cell comprising said vectors, a method of producing the polypeptide of SEQ ID NO:6, 8 and 13 and the polypeptide of SEQ ID NO:6, 8 and 13

Group II. Claim 40, 42, drawn to an antibody that binds to the polypeptide of SEQ ID NO:8.

Group III. Claim 41, 43, drawn to an antibody that binds to the polypeptide of SEQ ID NO:13.

Claim objections

3. Claims 21-23, 26-32 and 39 are objected to because of the following informalities:

3a. Claims 21-23 are objected to as using improper/incomplete Markush language. (See M.P.E.P. 706.03(y).) Applicants should delete ";" and substitute "and", as the last alternative embodiment, after ICAM-1 of sub-part (b) in each claim. Appropriate correction is required.

3b. Claims 26, 30, 31, 32 and 39 should recite “the” instead of “a” or “an” before DNA.

3c. Claims 27, 28 should recite “a” before DNA.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. Claims 24-25, 32-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 24-25 recite "A DNA that encodes a polypeptide ...." and claims 32-35 recite " A polypeptide comprising ...." both of these phrases encompass the nucleic acid and the polypeptide as they occur in nature. However, since Applicants do not intend to claim a naturally occurring product amendment of the claims to show the hand of man would obviate this rejection. It is suggested that claims 24-25 and 32-35 be amended to recite " an isolated DNA or an isolated polypeptide....."Appropriate correction is required.

Claim rejections-35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 21-23, 26, 29, 36-37, 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule comprising the nucleotide sequence set forth in SEQ ID NO:5, 7 or 12 , said nucleic acid encoding the polypeptide of SEQ ID NO:6, 8 and 13 respectively, does not reasonably provide enablement for an isolated polynucleotide encoding a fragment or a soluble fragment of SEQ ID NO:8 or 13, wherein said fragment is active in IKIBα or p38 MAP kinase phosphorylation or in cell surface expression of

ICAM-1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 21, 22 and 23 as currently drafted broadly encompass an isolated polynucleotide encoding a fragment of SEQ ID NO:8 or 13, wherein said fragment is active in IKIBα or p38 MAP kinase phosphorylation or in cell surface expression of ICAM-1, and claims 36-37 recite a soluble fragment of the polypeptide of SEQ ID Nos: 8 and 13, wherein said soluble fragment is active in IKIBα or p38 MAP kinase phosphorylation or in cell surface expression of ICAM-1. However, instant specification does not disclose a single fragment (soluble or not) of the polypeptides of SEQ ID Nos: 8 or 13 which is active in IKIBα or p38 MAP kinase phosphorylation or in cell surface expression of ICAM-1. The specification discloses the full length human IL-1 epsilon DNA sequences in SEQ ID Nos: 7 and 12, and the encoded polypeptides as SEQ ID Nos: 8 and 13, respectively, (see Example I, on page 47, lines 10-17). The specification also discloses that human IL-1 epsilon polypeptides were transfected into COS cells and showed that conditioned medium containing human IL-1 epsilon activated IKIBα and p38 MAP kinase phosphorylation in number of human cell lines including Human Foreskin Fibroblasts (HFF) and Human Umbilical Vein Endothelial cells, (see Example III on page 48). The specification also demonstrates that HFF cells incubated in conditioned medium from cells that had been transfected with IL-1 epsilon exhibited a two fold increase in cell surface expression of ICAM-1 levels, (see page 50, lines 6-12). However, instant specification does not disclose any fragment of the polypeptides of SEQ ID Nos: 8 or 13 which exhibits the activities of the full length human IL-1 epsilon. Instant specification asserts that

fragments of the claimed polypeptides can be used as molecular weight markers and describes relative molecular weights of fragments generated from cleavage of SEQ ID Nos: 8 by cyanogen bromide, (see page 35, lines 5-13). However, there is no disclosure of a fragment of SEQ ID NO:8 or 13, soluble or otherwise which is active in the aforementioned assays. The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant application, the quantity of experimentation to determine which fragments of SEQ ID Nos: 8 or 13 would retain the activity of the full length polypeptides is enormous and instant specification provides no guidance as to which amino acid residues are necessary for the functional integrity of the proteins. Absent further guidance from the specification it would constitute undue experimentation to determine which fragments if any of the polypeptides of SEQ ID Nos: 8 and 13 would be active in IKIBα or p38 MAP kinase phosphorylation or in cell surface expression of ICAM-1. Furthermore, one of ordinary skill in the art would not reasonably predict which fragments of the polypeptides of SEQ ID Nos:8 and 13 would retain the activity of the native protein. As such, claims 21-23 and 36-37 are not commensurate in scope with the specification but rather are broader than the supporting disclosure.

Claims 26, 29, 38 are rejected under 35 U.S.C. 112, first paragraph, insofar as they depend on claim 21 for the "fragment limitation" discussed above.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6a. Claims 21-23, 26, 29, 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 21-23, 36-37 the phrase ".....a fragment .....", renders the claims unclear and indefinite, because it is unclear which fragment of SEQ ID Nos: 8 and 13 is being claimed, how long should the claimed fragment be? The metes and bounds of the claims can not be ascertained. Appropriate correction is required.

Claims 26, 29, 38 are rejected under 35 U.S.C. 112, second paragraph, as bing vague and indefinte insofar as they depend on claim 21 for the "fragment limitation" discussed above.

Conclusion

7. Claims 27, 28, 30, 31 and 39 will be allowable, if overcome the minor objection.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursdays from 7:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud

Art Unit: 1647

Patent Examiner
Art Unit 1647
24 June 2002

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
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